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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,499	07/26/2001	David Hung	05284.00096	6261
38732	7590	09/08/2004		
CYTYC CORPORATION 85 SWANSON ROAD BOXBOROUGH, MA 01719			EXAMINER SIRMONS, KEVIN C	
			ART UNIT 3763	PAPER NUMBER

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/912,499	HUNG, DAVID
	Examiner	Art Unit
	Kevin C. Sirmons	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

#### A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 30 June 2004.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-13, 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-8, 11, 13, 26 and 27 is/are rejected.
- 7) Claim(s) 9, 10 and 12 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the means to measure a quality of the ductal fluid in situ and a MEMS must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 13 rejected under 35 U.S.C. 102(b) as being anticipated by Pestes et al U.S. Pat. No. 5,623,942.

Pestes discloses a flexible probe (12) having a diameter sized to access a breast duct (12) and a distal portion being capable of contacting an interior lumen of a breast duct and retrieving a sample of the breast duct fluid from within the duct for analysis (distal end of 10), and wherein said probe is free of an opening through which a fluid form an external source can be introduced into said probe and pass through said probe into the duct when said probe is

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positioned within the breast duct (fig. 1); as to claims 2-6, (distal end of 10). As to claim 13, (nylon).

Note: Hung et al U.S. Pat. No. 6,391,026 is being used as evidence to support the examiner position that Pestes discloses a flexible probe having a diameter sized to access a breast duct and a distal portion capable of contacting an interior lumen of a breast duct. Hung discloses a catheter suitable for accessing ductal lumens with a distal tip having a outer diameter of about 0.8 mm or 0.08 cm. Pestes discloses the same diameter of 0.08 cm (emphasis added). Therefore, it is quite clear that the device of Pestes is capable of performing the function as set forth in claim 1.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-8, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pestes U.S. Pat. No. 5,623,942 in view of Nicholson et al U.S. Pat. No. 4,616,656.

Pestes discloses a device for collecting breast duct fluid substantially as claimed except for a means (marker/indicia) to measure a quality of the ductal fluid in situ. Nicholson et al discloses a means (marker/indicia) to measure a quality of the ductal fluid in situ (col. 4. lines 12-17).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the distal portion of Pestes with the means to measure a quality of the ductal fluid as taught by Nicholson for providing markings to indicate the depth of the device distal end when anchored. Note: applicant indicates that his quality/means can comprise a marker (page 4, line (8)).

Pestes discloses a device for collecting breast duct fluid substantially as claimed except for a probe diameter between 0.008 cm to about 0.045 cm. Pestes discloses a probe with a diameter 0.08 cm. It would have been an obvious matter of design choice to one having ordinary skill in the art at the time the invention was made to have various diameter of the probe, since it has been held that such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. Furthermore, applicant has not disclosed that the various diameters solves any stated problem in the art or is for any particular purpose and it appears that the invention of Pestes would perform equally well.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pestes U.S. Pat. No. 5,623,942 in view of Marchosky et al U.S. Pat. No. 4,947,842.

Pestes discloses the device substantially as claimed except for a coating of an anesthetic on the exterior of the probe. Marchosky discloses an anesthetic coating on the exterior of the probe. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Pestes with the coating as taught by Marchosky to relieve pain in the treatment of tumors particularly in the area of the breast (col. 5).

***Allowable Subject Matter***

Claims 9, 10 and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

Applicant's arguments filed 6/30/04 have been fully considered but they are not persuasive.

***Drawings***

The objections to the drawings are maintained because the drawings must show every feature of the invention specified in the claims. Therefore, the means to measure a quality of the ductal fluid in situ and a MEMS must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

As to applicant's arguments on page 2 and 3, Hung et al U.S. Pat. No. 6,391,026 is being used as evidence to support the examiner position that Pestes discloses a flexible probe having a diameter sized to access a breast duct and a distal portion capable of contacting an interior lumen of a breast duct. Hung discloses a catheter suitable for accessing ductal lumens with a distal tip having a outer diameter of about 0.8 mm or 0.08 cm. Pestes discloses the same diameter of 0.08 cm (emphasis added).

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Therefore, it is quite clear that the device of Pestes discloses all of the structure and is capable of performing the function as set forth in claims. Furthermore, the size of the breast duct is not limited by applicant specification. Clearly the prior art discloses a breast duct with diameter of 1 mm or larger (figs. 3A and 4A of Hung).

As to applicant's arguments to the 103 rejections, clearly Nicholson discloses a means (marker/indicia) to measure a quality of the ductal fluid (26). The markings disclosed in (col. 4, lines 12-17) is not limited to depth, but could also be used to measure cell size, cell density, nuclear size and nucleoli size. Applicants own specification supports the examiner rational because pages 7 and 8 clearly state the markers and indicia (like the one disclosed in Nicholson) can be used to perform such acts. Applicant has provided no structure to distinguish his markers and indicia from Nicholson markers and indicia. Therefore, they are equivalent.

In summary the device of Nicholson is not being used in combination with Pestes. Only the concept of the markers is being combined with Pestes for the purpose of measuring quality!

### *Conclusion*

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

Kevin C. Sirmons  
Patent Examiner

9/2/04

